Platelet Collection

AMICUS Separator Kit Performance Report

Important: If reaction or injury has occurred call Fresenius Kabi Post-Market Quality Assurance at 1-800-933-6925.

Incident Date: _____ Instrument S/N.: _____ Software Version: ____ UDI No.: _____
Product Code: _____ Lot No.: _____ PAS: No ☐ Yes ☐ (Lot No.: _____) WB Processed: _____ mL

When Was the Problem Detected?

☐ Set Up ☐ Collection ☐ Plasma Transfer
☐ Prime _____% ☐ Reinfusion ☐ After Procedure/QC

Problem Type (*Mark all applicable*) ☐ Cut/Slice ☐ Kink ☐ Particulate Matter ☐ Restriction/No Flow
☐ Alarms (Specify) _____ ☐ Leak ☐ Platelet Aggregation (After 24 Hrs.) ☐ Separated
☐ Blood Leak ☐ Cracked ☐ Excess Air ☐ Missing ☐ RBC Contamination ☐ Other (Specify Below)

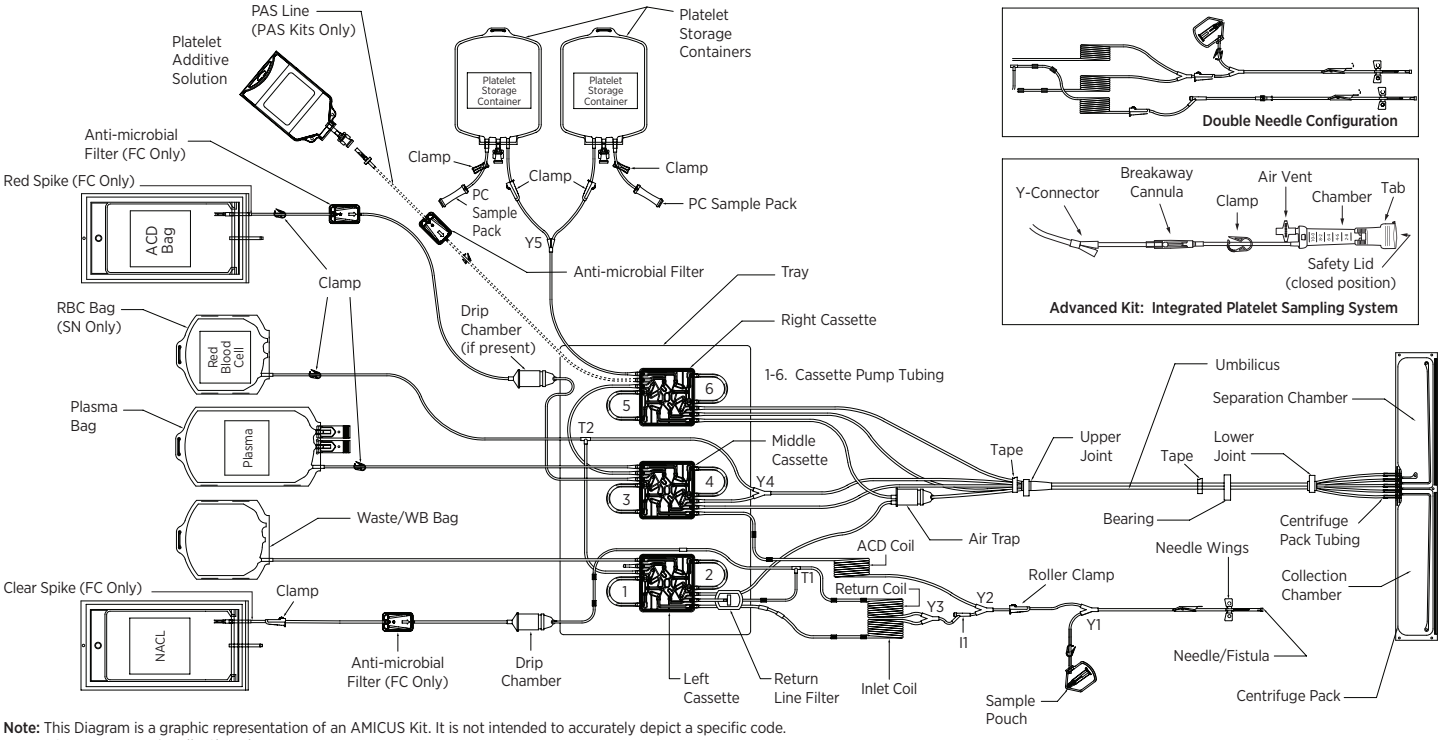
Please answer the following questions:

1. Was there any adverse event or injury? Yes ☐ No ☐
2. Was the procedure successfully completed? Yes ☐ No ☐ N/A ☐
3. If no, was the procedure stopped due to a soft goods incident? Yes ☐ No ☐ N/A ☐
4. Was product lost? Yes ☐ No ☐ N/A ☐

Check box if you do **NOT** wish to receive response letters. ☐

_____
E-mail address for letter recipient (if applicable)

Please circle specific components on the diagram where incident occurred



Note: This Diagram is a graphic representation of an AMICUS Kit. It is not intended to accurately depict a specific code.
Note: FC means "Functionally Closed."

Additional Problem Description / Explanation

_____

Kit Return To Fresenius Kabi

1. Sample available for evaluation? Yes ☐ No ☐
2. Sample return box needed? Yes ☐ No ☐ Return label only ☐
3. Picture available for evaluation? Yes ☐ No ☐
   Please e-mail a clear picture **along with this report** to **MDComplaintSupport@fresenius-kabi.com**

Center Authorized Signature/Date:

Fax this report to 1-888-858-2983 or E-mail to MDComplaintSupport@fresenius-kabi.com and include a copy of this form when returning a kit.

Customer Information (please print)

The following information is required to receive a credit

Facility Name: _____
Contact Person: _____
Account Number (if known): _____
Operator Name: _____
Street Address: _____
City/State/Zip: _____
Phone Number: _____
Contact Person's E-mail: _____